

## Light and Laser Therapy (for Louisiana Only)

Policy Number: CS069LA.L  
Effective Date: November 1, 2020

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### Application

This Medical Policy only applies to the state of Louisiana.

### Coverage Rationale

Pulsed dye laser therapy is proven and medically necessary for treating the following:

- Port-wine stains
- Cutaneous hemangiomata

Light and laser therapy including but not limited to intense pulsed light, light phototherapy, photodynamic therapy, and pulsed dye laser are unproven and not medically necessary for treating the following due to insufficient evidence of efficacy:

- Rosacea
- Rhinophyma
- Acne vulgaris

Laser hair removal is unproven and not medically necessary for treating pilonidal sinus disease due to insufficient evidence of efficacy.

### Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
<b>Cutaneous Vascular Lesion</b>	
17106	Destruction of cutaneous vascular proliferative lesions (e.g., laser technique); less than 10 sq cm
17107	Destruction of cutaneous vascular proliferative lesions (e.g., laser technique); 10.0 to 50.0 sq cm
17108	Destruction of cutaneous vascular proliferative lesions (e.g., laser technique); over 50.0 sq cm
<b>Laser Hair Removal</b>	
17380	Electrolysis epilation, each 30 minutes

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Diagnosis Code	Description
<b>Cutaneous Vascular Lesion</b>	
D18.00	Hemangioma unspecified site
D18.01	Hemangioma of skin and subcutaneous tissue
I78.0	Hereditary hemorrhagic telangiectasia
I78.1	Nevus, non-neoplastic
Q82.5	Congenital non-neoplastic nevus
Q85.8	Other phakomatoses, not elsewhere classified
Q85.9	Phakomatosis, unspecified

## Description of Services

### Port-Wine Stains and Hemangiomata

Port-wine stains (PWS) are a type of vascular lesion involving the superficial capillaries of the skin. At birth, the lesions typically appear as flat, faint, pink macules. With increasing age, they darken and become raised, red-to-purple nodules and papules in adults.

Congenital hemangiomas are benign tumors of the vascular endothelium that appear at or shortly after birth. Hemangiomas are characterized by rapid proliferation in infancy and a period of slow involution that can last for several years.

Lasers are used to treat both PWS and hemangiomas. The flashlamp-pumped pulsed dye laser (PDL) was developed specifically for the treatment of cutaneous vascular lesions. It emits one specific color, or wavelength, of light that can be varied in its intensity and pulse duration. Cryogen spray cooled PDL (CPDL) involves the application of a cryogen spurt to the skin surface milliseconds prior to laser irradiation. This cools the epidermis without affecting the deeper PWS blood vessels, and reduces the thermal injury sustained by the skin during laser treatment. The goals of PDL therapy are to remove, lighten, reduce in size, or cause regression of the cutaneous vascular lesions in order to relieve symptoms and alleviate or prevent medical or psychological complications.

### Rosacea and Rhinophyma

Rosacea is a chronic cutaneous disorder primarily affecting the central face, including the cheeks, chin, nose, and central forehead. It is often characterized by remissions and exacerbations. Based on current knowledge, rosacea is considered a syndrome or typology, and exhibits various combinations of cutaneous signs such as flushing, erythema, telangiectasia, edema, papules, pustules, ocular lesions, and rhinophyma. Monochromatic (i.e., laser) therapies are increasingly being considered for treatment of the signs and symptoms associated with rosacea, including the PDL, high-energy 532 nm pulse potassium titanyl phosphate (KTP) laser, and a variety of intense pulsed light (IPL) sources (Hayes, 2018; updated 2020).

Rhinophyma is a disfiguring condition of the external nose characterized by tissue hypertrophy, dilated follicles, and irregular nodular overgrowth. Although the etiology of rhinophyma remains unknown, it typically appears in the later stages of rosacea and forms gradually over years. A variety of surgical techniques including cryosurgery, electrosurgery, dermabrasion, scalpel and razor blade excision, and laser surgery have been used to reduce visible blood vessels and remove rhinophymatous tissue.

## Acne Vulgaris

Acne vulgaris (AV) is a common skin condition associated with obstruction and inflammation of the hair follicle and sebaceous glands. This may result in the formation of comedones, papules, pustules, nodules, and cysts. Acne is a multifactorial inflammatory disease, and the current understanding of acne pathogenesis is continuously evolving (Zaenglein et al., 2016). Light and laser therapies are being considered to treat acne. Light therapy is defined as exposure to nonionizing radiation for therapeutic benefit. It can include the use of phototherapy, IPL, and photodynamic therapy (PDT). PDT is the use of visible light in addition to a topical application of a photosensitizer, such as 5-aminolevulinic acid (ALA) or methyl aminolaevulinate (MAL). Laser types that are being studied to treat acne include near-infrared laser, PDL, long-PDL, argon laser, smooth beam laser, and diode laser.

## Pilonidal Sinus Disease

Pilonidal sinus disease is a chronic infection in the skin that occurs slightly above the crease between the buttocks. It develops into a cyst called a pit or sinus. Hair may protrude from the pit, and several pits may be seen. Because the cause of pilonidal sinus disease has been attributed to hair follicle ingrowth, laser hair removal (LHR) or laser hair depilation (LHD) has been proposed as an adjunct or alternative to surgery. Although originally thought to be congenital in nature secondary to abnormal skin in the gluteal cleft, the current widely accepted theory describes the origin of pilonidal disease as an acquired condition intimately related to the presence of hair in the cleft (Steele, et al., 2013).

# Clinical Evidence

## Port-Wine Stains (PWS) and Hemangiomas

According to a Comparative Effectiveness Review of IH prepared for the Agency for Healthcare Research and Quality (AHRQ), limited research is available to guide decision-making about the use of laser modalities as the initial intervention. The advent of propranolol has largely relegated laser treatment to secondary management. There is little comparative data between lasers and beta-blockers, however the success rates for complete or near complete resolution in historical laser studies are notably lower than those in more recent propranolol studies. Under current treatment paradigms, PDL with epidermal cooling is most often used for residual cutaneous changes after the completion of the proliferative growth phase and with incomplete resolution after pharmacologic management, while Nd:YAG laser is most often used intralesionally for medically refractory lesions. A variety of other lasers are used for intralesional treatment or resection, though no conclusions can be drawn regarding the superiority of any of these modalities over any other. According to the review, laser studies generally found PDL more effective than other types of laser, but effects remain unclear as studies are heterogeneous and the role of laser vis-a-vis beta-blockers is not clearly described in the literature (Chinnadurai et al., 2016a).

Chinnadurai et al. (2016b) systematically reviewed studies of laser treatment of infantile hemangioma (IH). A total of 29 studies addressing lasers: 4 randomized controlled trials (RCTs), 8 retrospective cohort studies, and 17 case series were identified. Lasers varied across studies in type, pulse width, or cooling materials. Most comparative studies (n=9) assessed variations of PDL and examined heterogeneous endpoints. Most studies reported on treatment of cutaneous lesions. CO<sub>2</sub> laser was used for subglottic IH in a single study, and was noted to have a higher success rate and lower complication rate than both Neodymium: Yttrium-Aluminum-Garnet (Nd:YAG) and observation. Studies comparing laser with  $\beta$ -blockers or in combination with  $\beta$ -blockers reported greater improvements in lesion size in combination arms versus  $\beta$ -blockers alone and greater effects of lasers on mixed superficial and deep IH. Strength of the evidence for outcomes after laser treatments ranged from insufficient to low for effectiveness outcomes. Strength of the evidence was insufficient for the effects of laser compared with  $\beta$ -blockers or in combination with  $\beta$ -blockers as studies evaluated different agents and laser types. Studies assessing outcomes after CO<sub>2</sub> and Nd:YAG lasers typically reported some resolution of lesion size, but heterogeneity among studies limited the ability to draw conclusions. The authors concluded that studies of laser treatment of IH primarily addressed different laser modalities compared with observation or other laser modalities. PDL was the most commonly studied laser type, but multiple variations in treatment protocols did not allow for demonstration of superiority of a single method. Most studies reported a higher success rate with longer pulse PDL compared to observation in managing the size of IH, although the magnitude of effect differed substantially. Studies generally found PDL more effective than other types of lasers for cutaneous lesions. When first introduced as a primary treatment for IH, various laser modalities generally offered superior outcomes compared with steroid therapy and observation. According to the authors, in the era of  $\beta$ -blocker therapy, laser treatment may retain an important role in the treatment of residual and refractory lesions.

Shen et al. (2015) conducted a meta-analysis to review the therapeutic efficacy and safety of PDL in the treatment of IH. A total of 13 articles with 1529 hemangiomas were included in the meta-analysis. This meta-analysis demonstrated an overall resolution rate of 89.1% with 6.28% incidence of AE. The authors concluded that PDL may be the effective modality to decrease the proliferative phase and accelerate rates of involution and resolution with few AEs.

Chen et al. (2015) retrospectively summarized the use of PDL in infant patients with superficial hemangioma, who had received 595 nm tunable PDL treatment in the last 10 years. Detailed demographics, results of assessment about their degree of clearance and clinical examination for treatment complications were entered into SASS 10.0 version database, and statistical analyses were conducted. Six hundred and fifty-seven cases with superficial hemangioma were recruited. The overall effectiveness rate was 91.17%. Female patients responded better than male; the difference was statistically significant. Lesions in different parts of the body respond differently to the treatment, with lesions on extremities showing the best result. The response rate does not increase with time of treatments. The most common AEs were pigment changes and skin atrophy, which usually resolved spontaneously and disappear completely in a few months. The authors concluded that their experience confirmed the satisfactory clinical efficacy and safety of the 595 nm tunable PDL in the treatment of childhood superficial hemangioma.

Faurschou et al. (2009) conducted a randomized side-by-side trial to compare efficacy and AEs between PDL and IPL in treating PWS. Twenty patients with PWS (face, trunk, extremities; pink, red and purple colors; skin types I-III) received one side-by-side treatment with PDL (V-beam Perfecta, 595 nm, 0.45-1.5 ms; Candela Laser Corporation, Wayland, MA, U.S.A.) and IPL (StarLux, Lux G prototype handpiece, 500-670 and 870-1400 nm, 5-10 ms; Palomar Medical Technologies, Burlington, MA, U.S.A.). Settings depended on the preoperative lesional color. Treatment outcome was evaluated by blinded, clinical evaluations and by skin reflectance measurements. While both technologies lightened the PWS and no AEs were observed with either device, the authors concluded that the PDL resulted in better efficacy and higher patient preference.

## ***Professional Societies***

### **American Academy of Pediatrics (AAP)**

AAP clinical practice guidelines for the management of infantile hemangiomas state that clinicians may recommend laser therapy as a treatment option in managing select IHs (grade C, moderate recommendation). Decisions regarding use should be made in consultation with a hemangioma specialist, especially in young infants. Laser treatment may be most useful for the treatment of residual skin changes after involution and, less commonly, may be considered earlier to treat some IHs. The guidelines also note that, with the advent of beta-blocker therapy, laser approaches are used less frequently (Krowchuk et al., 2019).

### **Acne Vulgaris**

There is insufficient evidence to recommend the use of light and laser therapy for the treatment acne vulgaris. Studies evaluating light and laser therapy for acnetypically are short term, lack controls or the study participants serve as their own control, have small sample sizes, and do not compare laser therapy with standard acne treatment. Well-designed studies are necessary to clarify the role of light and laser therapy for acne.

Scott et al. (2019) performed a systematic review and meta-analysis of studies assessing the effectiveness of blue-light therapy for acne. Fourteen trials (N=698) were included. Only three of the trials reported significant improvements in investigator-assessed acne severity with blue light therapy over a control group. Patient-assessed improvements were reported in two studies that favored blue light. Mean difference in the mean number of noninflammatory (open and closed comedones) and inflammatory lesions (papules, pustules, nodules) was nonsignificant between the groups at several time points and overall. Adverse events were generally mild and favored blue light or did not significantly differ between groups. Methodological and reporting limitations of existing evidence limit conclusions about the effectiveness of blue light for acne. Limitations included small sample sizes, short intervention periods, and high risk of bias.

In a systematic review, de Vries et al. (2018) assessed the efficacy and safety of non-pharmacological therapies in the treatment of acne vulgaris (AV). These included laser- and light-based therapies, chemical peels and fractional microneedling radiofrequency. Seven studies were considered to include a high methodological quality and included in the best evidence synthesis. Moderate evidence was found for IPL (400-700 and 870-1200 nm) and the diode laser (1450 nm). Initially, conflicting evidence was found for PDL (585-595 nm). Circumstantial evidence was the basis for non-pharmacological therapies in the

treatment of AV, for which the authors were unable to draw clear conclusions. They concluded that these outcomes provide a first step in future research.

Boen et al. (2017) performed a systematic review of the literature for PDT used for acne and critically evaluated the studies. Sixty-nine clinical trials, 4 case reports, and 2 retrospective studies met the inclusion criteria. Seven of the studies were high quality. The most common photosensitizers used were 5-ALA and MAL, and both showed similar response. Red light was the most frequently used light source, followed by IPL, and showed comparable results. Inflammatory and non-inflammatory lesions both responded to treatment, with inflammatory lesions showing greater clearance in most studies. AEs associated with PDT for acne were mild and included pain on illumination and post-procedural erythema and edema. The authors indicated that this review supports PDT as an efficacious treatment for acne and a good adjunctive treatment for mild to severe acne, especially in patients who have not responded to topical therapy and oral antibacterials and are not great candidates for isotretinoin. According to the authors, further studies are warranted to evaluate the optimal photosensitizers, light sources, incubation times, and number of treatments for PDT use in acne.

A Cochrane review conducted by Barbaric et al. (2016) evaluated the effects of light treatment of different wavelengths for acne. Seventy-one RCTs (4211 participants, median sample size 31) were included in the review. Light interventions differed greatly in wavelength, dose, active substances used in PDT, and comparator interventions (most commonly no treatment, placebo, another light intervention, or various topical treatments). Numbers of light sessions varied from one to 112 (most commonly two to four). Frequency of application varied from twice daily to once monthly. Selection and performance bias were unclear in the majority of studies. Two thirds of studies were industry-sponsored; study authors either reported conflict of interest, or such information was not declared, so the risk of bias was unclear. Results from a single study (N=266, low quality of evidence) showed little or no difference in effectiveness on participants' assessment of improvement between 20% aminolevulinic acid (ALA) PDT, activated by blue light, versus vehicle plus blue light, whereas another study (N=180) of a comparison of ALA-PDT (red light) concentrations showed 20% ALA-PDT was no more effective than 15%, but better than 10% and 5% ALA-PDT. Pooled data from three studies, (N=360, moderate quality of evidence) showed that methyl aminolevulinate (MAL)-PDT, activated by red light, had a similar effect on changes in lesion counts, compared with placebo cream with red light. Several studies compared yellow light to placebo or no treatment, infrared light to no treatment, gold-microparticle suspension to vehicle, and clindamycin/benzoyl peroxide (C/BPO) combined with PDT to C/BPO alone. None of these showed any clinically significant effects. Although the primary endpoint of the review was long-term outcomes, less than half of the studies performed assessments later than 8 weeks after final treatment. Only a few studies assessed outcomes at more than three months after final treatment. The authors concluded that high-quality evidence on the use of light therapies for individuals with acne is lacking. There is low certainty of the usefulness of MAL-PDT (red light) or ALA-PDT (blue light) as standard therapies for people with moderate to severe acne. According to the authors, carefully planned studies, using standardized outcome measures, comparing the effectiveness of common acne treatments with light therapies are needed.

Keyal et al. (2016) evaluated the evidence regarding safety and efficacy of PDT in treating acne lesions. Thirty-six clinical trials were included in the review. Twenty-four of these trials were performed to evaluate the effect of PDT in acne and 12 trials were performed to compare the effect of PDT with light or laser alone therapy. Among 24 trials that used PDT only, 3 were clinical trials with control, 14 were clinical trials without control, 6 were RCTs and 1 was retrospective study. The authors concluded that PDT is an effective treatment modality for acne lesions. However, more RCTs are needed to establish standard guidelines regarding concentrations and incubation period of photosensitizers and optimal parameters of light sources. There is also paucity of studies that could identify whether PDT can be a first line treatment for severe acne or only an alternative to medical treatment for non-responders. Moreover, RCT comparing conventional therapy with PDT are highly needed.

Antoniou et al. (2016) conducted a 12-week multicenter, split-face RCT to evaluate the efficacy and safety of the KLOX BioPhotonic System, a LED blue light phototherapy device using specific photo-converter chromophores, in the treatment of moderate to severe ac. A total of 104 patients with moderate to severe acne were eligible for inclusion in the study and screened for enrolment. Of these, 98 (94%) were randomized and 90 (92%) underwent at least one treatment session. Five patients decided to withdraw their consent before receiving a first treatment, and 3 patients were not treated as the study enrollment period was ended. Efficacy was assessed through changes in acne severity using the Investigator's Global Assessment (IGA) scale and inflammatory acne lesion counts, both evaluated against baseline at weeks 6 and 12. Safety was assessed through physical exam, vital signs, laboratory evaluations, and physician and patient reporting of AEs. A reduction of at least two grades in IGA scale severity was demonstrated in 51.7% of patients at week 12. Furthermore, at week 12, subjects with a baseline IGA grade of 3 (moderate) demonstrated a success rate (2 or greater grade drop) of 45.3% whereas patients with a baseline IGA grade of 4 (severe) demonstrated a success rate of 61.1%. Acne inflammatory lesion counts confirmed

these results, with a reduction of at least 40% of lesions in 81.6% of treated hemi-faces after 12 weeks. Treatment was considered as safe and well tolerated, with no serious AEs and no patient discontinuation from the study from any AE. The authors concluded that the BioPhotonic System comprised of LED blue-light phototherapy was efficacious and safe, with a sustained clinical response at 12 weeks for the management of moderate to severe facial inflammatory acne. According to the authors, study limitations include the absence of an established active acne topical agent as a control group. Another limitation of the study is that the majority of included patients were female, so the results mostly apply to this population.

Mohamed et al. (2016) compared the clinical efficacy of intense pulsed light (IPL) versus 1,064 long-pulsed Nd:YAG in treatment of facial AV. Seventy-four patients were enrolled in this prospective, split-face, RCT. All participants received 3 sessions of IPL on the right side of the face and 1,064-nm Nd:YAG on the left side of the face at 4-weeks intervals. Final assessment was made by comparison of the changes in the count of inflammatory acne lesions (inflammatory papules, pustules, nodules and cyst) and non-inflammatory acne lesions (comedones) and the acne severity score between both therapies, based on standardized photography. At the final visit, the inflammatory acne lesions were reduced on the IPL and 1,064-nm Nd:YAG treated sides by 67.1% and 70.2% respectively, while non-inflammatory acne lesions were reduced by 18.3% and 19.3% respectively. For both therapies, there was significant difference in the improvement on inflammatory acne lesions in comparison to non-inflammatory lesions. There was no significant difference in the efficacy of the two therapies in reducing the percentage of both types of acne lesions count from baseline to the end of the study. The authors concluded that both IPL and 1,064-nm Nd:YAG laser are effective in treatment of inflammatory facial AV. Study limitations include the absence of an established standard therapy as a control group.

In a systematic review, Wat et al. (2014) reviewed the evidence to provide recommendations to guide physicians in the application of IPL for the treatment of dermatologic disease. Studies that examined the role of IPL in primary dermatologic disease were identified, and multiple independent investigators extracted and synthesized data. Recommendations were based on the highest level of evidence available. Level 1 (moderate to high) evidence was found for the use of IPL for the treatment of AV. The authors concluded that IPL is an effective treatment modality for a growing range of dermatologic disease and in some cases may represent a treatment of choice. According to the authors, the main limitation of this review was the general lack of high-quality studies. Almost all of the reviewed studies were limited by the number of patients enrolled (usually <100) and by the length of follow-up (typically  $\leq 6$  months). Long-term outcome analysis is needed. Additionally, the wide variety of IPL devices, device settings, patient demographic characteristics, and user expertise detracted from a completely homogeneous assessment of the data. According to the authors, further large-scale, high-quality studies are needed to optimally delineate exact treatment parameters for specific diseases.

In an evidence-based review, Zheng et al. (2014) assessed the effects and safety of PDT for acne. A total of 14 RCTs involving 492 patients were included. Photosensitizers included ALA, MAL, and indole-3-acetic acid (IAA). Light sources included red light, PDL, IPL, long-pulsed dye laser (LPDL) and green light. The PDT protocols, including ALA + red light, ALA + PDL, ALA + IPL, MAL + red light, and MAL + LPDL, all showed great efficacy on inflammatory lesions. ALA + red light also had effects on non-inflammatory lesions and sebum secretion. ALA + IPL and IAA + green light significantly decreased sebum secretion. Triple treatment protocols showed great improvement on inflammatory and non-inflammatory lesions. Increasing ALA concentration, ALA incubation time, PDT sessions, dose of light source or using occlusion for photosensitizers, or a combination of other treatments with PDT may achieve greater efficacy. The common side effects of PDT were tolerable and transient. The authors concluded that limited evidence indicates that PDT shows good efficacy in the treatment of acne with acceptable side effects. ALA + red light was shown to be the optimal choice. According to the authors, more RCTs are needed to determine the types and concentrations of photosensitizers and light sources, and the duration of light activation and incubation.

Erceg et al. (2013) systematically reviewed the literature concerning PDL treatment for inflammatory skin diseases including AV. The authors concluded that PDL treatment can be recommended as an effective and safe treatment for AV (recommendation grade B). The authors noted that despite the promising results found in studies, it is still unclear whether PDL treatment for acne will become a standard treatment in the future. The authors state that no large intra-patient, split-face comparative studies were done with PDL treatment in comparison with other well-established, easily accessible treatments, so the added value to conventional forms of therapy is still unclear. The authors stated that the conclusions formulated from the systematic review are not based on RCTs.

EI-Latif et al. (2013) compared the clinical efficacy of IPL therapy versus benzoyl peroxide (BP) 5% for the treatment of inflammatory acne. Fifty patients (15 males and 35 females) aged 18-27 years, with mild-to-severe acne and Fitzpatrick skin phototype IV were enrolled in the study. The patients were equally divided into 2 groups. The first group was treated by BP

while the second group was treated by IPL. Treatment with both BP and IPL resulted in considerable improvement of the acne after 5 weeks of treatment. Comparing the effects of both therapies, BP produced better results than IPL. The difference in the results was statistically significant at the midpoint of the study. However, this difference was insignificant at the end of study.

Karsai et al. (2010) assessed the efficacy of adjuvant PDL treatment when combined with a proven topical treatment (C/BPO). Eighty patients were randomized in a 1 : 2 ratio to receive C/BPO alone or in combination with PDL treatment. Patients were evaluated at baseline and at 2 and 4 weeks after initial treatment. Both groups showed a significant improvement during observation, but there was no significant or otherwise appreciable difference between treatment modalities as far as the extent of improvement was concerned. Patients with more severe findings at baseline had a greater benefit from either therapy regimen. The authors concluded that their findings do not support the concept of a substantial benefit of PDL treatment in AV.

Other studies evaluating light and laser therapy for treating acne were limited by small sample size and short follow-up (Nikolis et al., 2018; Yazdi et al., 2017; Voravutinon et al., 2016; Ash et al., 2016; Moftah et al., 2016; Pariser et al., 2015; Liu et al., 2014a; Song et al., 2014; Moneib et al., 2014).

## ***Professional Societies***

### **American Academy of Dermatology (AAD)**

In a guideline of care for the management of AV, the AAD states that there is limited evidence to recommend the use and benefit of physical modalities for the routine treatment of acne, including PDL. According to the AAD, large, prospective, multicenter, randomized, double-blinded controlled trials comparing light and laser devices to placebo are needed. The AAD further states that comparative effectiveness clinical trials for safety and efficacy of different light and laser sources/wavelengths and which types of lesions they improve are also needed (Zaenglein et al., 2016).

### **Rosacea and Rhinophyma**

The quantity and quality of the evidence is insufficient to recommend light and laser treatment for the treatment of rosacea and rhinophyma. Additional research is needed to determine efficacy and safety and to clarify patient selection and treatment parameters.

The National Rosacea Society (NRS) developed a consensus document on management options for rosacea that includes an updated classification system based on phenotypes. The document addresses pulsed-dye laser and intense pulsed light therapies as established practice in removing telangiectasia and diminishing erythema; however, the NRS acknowledges the lack of quality clinical evidence to support these therapies and assigns a weak rating (Thiboutot et al., 2020).

A comparative effectiveness review by Hayes found there to be some limited evidence from several prospective, randomized studies that laser and light therapies may reduce the signs and symptoms of facial rosacea with relatively few AEs. The evidence also suggests that PDL is as effective as IPL therapy, Nd:YAG laser, and radiofrequency for treating symptoms of rosacea. However, the overall quality of evidence was low, and the few available studies were small, differed in patient selection criteria and treatment protocols, and most provided only short follow-up. There is uncertainty regarding the comparative efficacy of laser and light with other treatments and the optimal timing of therapy for the best management of symptoms, as well as questions regarding how laser and light therapies fit into the overall continuum of rosacea treatment and patient management, and how these therapies apply to each of the 4 rosacea subtypes. Additional research is needed to confirm the comparative efficacy and safety and to define appropriate patient selection criteria and optimal treatment parameters. (Hayes, 2018; updated 2020).

In a review of rosacea, van Zuuren (2017) summarized that although laser therapy and other light-based therapies are widely used in the treatment of erythema and telangiectasia, these methods of treatment have been investigated primarily in observational studies. The few randomized trials are limited by small sample sizes.

In a randomized, single-blinded, comparative study, Seo et al. (2016) compared the effectiveness of the dual wavelength long-pulsed 755-nm alexandrite/1,064-nm neodymium: yttrium-aluminum-garnet laser (LPAN) with that of 585-nm PDL for rosacea. Erythema index was measured by spectrophotometer, and digital photographs were evaluated by consultant dermatologists for physician's global assessment. Subjective satisfaction surveys and AEs were recorded. Forty-nine subjects with rosacea were enrolled in the study and 12 dropped out. Full face received four consecutive monthly treatments with LPAN or PDL, followed-up for 6 months after the last treatment. There were no significant differences between LPAN and PDL in the mean reduction of

the erythema index, improvement of physician's global assessment, and subject-rated treatment satisfaction. PDL showed more adverse effects including vesicles than LPAN. No other serious or permanent AEs were observed in both treatments. The authors concluded that both LPAN and PDL may be effective and safe treatments for rosacea. According to the authors, there are several limitations in the general application of the study findings. First, as with all studies comparing 2 devices, there is no way to be absolutely certain that the settings were comparable, since those have different parameters and laser settings. Second, because the spectrophotometer measured only small spots, erythema index might not reflect the entire severity of rosacea or facial erythema. Third, in subjects receiving LPAN treatments, it is difficult to determine the effect of each laser separately. Fourth, all the subjects were of Korean with darker skin types, which may limit the generalizability of the study. The authors state that future studies with split-face comparison, various laser settings, and comparison of long-pulsed alexandrite and PDL are necessary to establish the optimal treatment devices and settings for rosacea treatment.

A Cochrane review on interventions for rosacea (van Zuuren et al., 2015) found that PDL was more effective than Nd:YAG laser based on 1 study, and it appeared to be as effective as IPL therapy (both low quality evidence). The authors stated that there was low quality evidence for laser and IPL therapy for ocular rosacea.

In a systematic review, Wat et al. (2014) reviewed the evidence to provide recommendations to guide physicians in the application of IPL for the treatment of dermatologic disease. Studies that examined the role of IPL in primary dermatologic disease were identified, and multiple independent investigators extracted and synthesized data. Recommendations were based on the highest level of evidence available. Level 2 (moderate) evidence was found for the treatment of rosacea. The authors concluded that IPL is an effective treatment modality for a growing range of dermatologic disease and in some cases may represent a treatment of choice. According to the authors, the main limitation of this review was the general lack of high-quality studies. Almost all of the reviewed studies were limited by the number of patients enrolled (usually <100) and by the length of follow-up (typically ≤6 months). Long-term outcome analysis is needed. Additionally, the wide variety of IPL devices, device settings, patient demographic characteristics, and user expertise detracted from a completely homogeneous assessment of the data. According to the authors, further large-scale, high-quality studies are needed to optimally delineate exact treatment parameters for specific diseases.

Erceg et al. (2013) systematically reviewed the literature concerning PDL treatment for inflammatory skin diseases including rosacea. The authors noted that most conclusions formulated are not based on RCTs. The authors concluded that there is low level evidence for PDL treatment for papulopustular rosacea.

In a split-face, double-blind RCT, Alam et al. (2013) compared the effectiveness of microsecond 1064-nm Nd:YAG laser with non-purpuragenic 595-nm PDL for diffuse facial erythema or erythematotelangiectatic rosacea (ETR). Bilateral cheeks received 4 treatments each at one month intervals with PDL or Nd:YAG. Spectrophotometer measurements, digital photographs, pain scores, and patient preferences were recorded. Fourteen patients (57% women, mean age 42 years) completed the study and were analyzed. Spectrophotometer readings changed after both PDL (8.9%) and Nd:YAG (2.5%), but varied by treatment type, with PDL reducing facial redness 6.4% more from baseline than Nd:YAG. Pain varied, with Nd:YAG associated with less pain, at 3.07, than PDL at 3.87. Subjects rated redness as improved by 52% as a result of PDL, and 34% as a result of Nd:YAG. No serious adverse events were observed. The authors concluded that facial erythema is safely and effectively treated with PDL and Nd:YAG and that non-purpuragenic PDL may be more effective for lighter-skinned patients, but microsecond Nd:YAG may be less painful. According to the authors, future research may consider comparison of additional laser devices and settings. This study is limited by a small sample size.

Lazzeri et al. (2013) reviewed the long-term results of 67 patients affected by rhinophyma treated with 2 different methods. Forty-five patients were treated with tangential excision and 22 with a CO2 laser. Minor complications, including scarring and hypopigmentation, were seen in 6 patients. All patients were satisfied with their outcomes at the follow-up visit, and no major complications were detected during follow-up. The authors concluded that both tangential excision and carbon dioxide laser are well-established, reliable procedures for rhinophymaplasty that preserve the underlying sebaceous gland fundi allowing spontaneous re-epithelialization without scarring with similar outcomes and high patient satisfaction. According to the authors, the CO2 laser is more capital intensive and results in higher fees compared with the simpler cold blade tangential excision. The authors state that the ease of use, accuracy and precision of laser treatment is not justified by the increased costs. According to the authors, the disadvantage of the deep tissue laser penetration is that the laser may generate high thermal energy with resultant damage to the dermis and adnexa, with the associated risks of scarring, poor texture and pigmentation modifications.



Several published studies reported that light and laser therapy may be safe and effective for treating rosacea (Kim et al., 2017; Micali et al., 2018; Liu et al., 2014b) and rhinophyma (Bassi et al., 2016). Studies were limited by small sample size and study design.

### ***Professional Societies***

#### **American Academy of Dermatology (AAD)**

The AAD does not have a clinical guideline on the treatment of rosacea or rhinophyma.

#### **American Acne & Rosacea Society (AARS)**

The AARS issued consensus recommendations on the management of rosacea that state that laser systems, such as PDL and Nd:YAG, as well as IPL devices can be used to effectively treat persistently dilated superficial cutaneous vessels that are not responsive to medical therapies used for treatment of papulopustular rosacea, including linear telangiectases and more confluent telangiectatic networks. The authors also state that approaches for the treatment of rhinophyma may include laser ablation (Tanghetti et al., 2014).

### **Pilonidal Sinus Disease**

There is insufficient evidence to conclude that laser hair removal is effective for treating pilonidal sinus disease. Most of the studies regarding this treatment were small and uncontrolled. Additional well-designed controlled trials are needed to determine the efficacy of laser hair removal for pilonidal disease.

Halleran et al. conducted a systematic review of published literature analyzing laser hair depilation (LHD) in pilonidal disease to determine its effect on disease recurrence. Thirty-five published studies were included. Of these, 28 studies were retrospective and 7 were prospective. There were 5 comparative studies: 2 retrospective, 1 prospective observational, and 2 RCTs. The number of patients included in each study ranged from one to 86 patients and patients received between one and 11 laser treatments. The pilonidal disease recurrence rate after LHD ranged from 0% to 28% at a mean follow-up ranging from 6 months to 5 years across studies. Four of the five studies that included a comparative group demonstrated a decreased recurrence rate compared to the non-laser cohort. The reviewers concluded that LHD is a promising therapy in the management of pilonidal disease. However, the literature published to date is heterogeneous and has limited generalizability. Additional research is needed to determine the effectiveness of LHD to prevent pilonidal disease recurrence (2018).

Pronk et al. (2018) conducted a systematic review to determine the effect of LHD on the recurrence rate in patients surgically treated for pilonidal sinus disease. The search and selection yielded 14 studies, involving 963 patients. The study design of the included studies was retrospective cohort (N=7), prospective cohort (N=3), RCT (N=2), and case-control (N=2). The mean length of follow-up was 37 months. The recurrence rate was 9.3% (34 out of 366 patients) in patients who had laser hair removal, 23.4% (36 out of 154 patients) in those who had razor shaving/cream depilation, and 19.7% (85 out of 431 patients) in those who had no hair removal after surgery for pilonidal sinus disease. Although this review showed a lower recurrence rate after LHR compared to no hair removal, the sample size is small with limited methodological quality of the included studies. High quality RCTs are needed to validate these findings.

Lopez et al. (2017) conducted a prospective, single arm, pilot trial of LHD to the natal cleft to assess the safety and tolerability of the procedure in 13 adolescents with pilonidal disease. Each patient received an outpatient LHD treatment every four weeks with a goal of five total treatments. Follow-up tolerability was measured after each treatment by obtaining Likert scale, patient-reported, pain scores immediately after laser treatment and every six hours post-treatment, for the first 24 hours. The primary end point was tolerability and safety, defined as pain scores consistently <4 and no deep second-degree burns during the 24-hour post-treatment period. The secondary end point was disease recurrence at one year. Twelve patients completed 5 LHD sessions and one patient completed 4. There was 100% tolerability of treatments with no occurrence of second-degree burns. No patient was unable to complete a treatment session because of discomfort. Significantly diminished hair growth was noted after 3 treatments. All 13 patients were recurrence-free at a median follow-up of 13 months post-treatment initiation. Researchers concluded that LHD is safe and well tolerated in adolescents with pilonidal disease and may be effective at decreasing pilonidal disease recurrence. A prospective RCT is planned to determine effectiveness of LHD compared with chemical/mechanical depilation methods in preventing pilonidal disease recurrence.

Khan et al. (2016) conducted a retrospective study evaluating the use of LHD for treating 19 patients with recurrent pilonidal sinus following multiple surgical treatments. Patients received outpatient long-pulsed alexandrite laser for depilation in the sinus area. There was a significant reduction in hair density after laser treatment. The disease-free period after laser treatment was significantly longer than after surgical treatment alone. The average cost of repeated surgical treatment per disease-free month was significantly higher than that of laser treatment. According to the authors, compared to surgical treatment of recurrences, LHD is an efficient and cost-effective method of preventing recurrence and reducing morbidity and loss of man-hours. This study is limited by a small sample size and lack of a control group.

In a prospective RCT, Demircan et al. (2015) investigated the effects of LHD on patient satisfaction and recurrence in 60 patients who underwent pilonidal sinus surgery. Patients were divided in 2 groups of 30 patients each. Only the Karydakias flap reconstruction technique was performed in the first group. Two sessions of LHD were applied in the second group in addition to Karydakias flap reconstruction. The patients in the second group underwent LHD 2 weeks before and 3 weeks after the surgery for a total of 2 times in a private office. There were no statistically significant differences between the groups in terms of age, gender, smoking usage, American Society of Anesthesiologists Score, duration of patient's complaints, body mass index and hospital stay. There were no statistically significant differences between the groups in terms of surgical site infection, wound separation, or abscess formation postoperatively. There were statistically significant differences between the 2 groups in the first week post operation considering the visual analogue scale (VAS) pain score and VAS satisfaction score. While there were statistically significant differences between the 2 groups in the first month post operation considering the VAS pain score, there were no statistically significant differences between the groups in terms of VAS satisfaction score in the first and third month postoperatively. In telephone interviews done 1 year after the surgery, recurrence was detected in 4% of the first group and in 20% of the second group. Recurrence rates were significantly higher in the second group. The authors concluded that their results show that LDH does not reduce the relapse rates in pilonidal sinus surgery, as expected. According to the authors, additional prospective randomized studies need to be done to evaluate LDH.

Ghnnam and Hafez (2011) conducted a prospective randomized study that compared permanent LHR following the excision of pilonidal disease with conventional methods for hair removal. Patients undergoing surgery for pilonidal disease were randomized to 2: those using LHR methods following completed healing of wounds (group I, n=45) or regular post-healing conventional methods for hair removal, mainly razor and depilatory creams, for at least 6 months (group II, n=41). Group I patients received regular, monthly laser hair treatment sessions using Alexandrite laser for four sessions. Group I patients found the procedure comfortable with no complications. Group II patients reported difficulty in maintaining hair removal with conventional methods, and mostly, by the end of the first year, all cases stopped maintaining regular hair removal. There was no significant difference between the groups in the recurrence rate (0% for laser versus 4.4% for standard hair removal methods). Recurrence occurred in Group II patients (2 cases) mostly due to failure in maintaining hair removal and area hygiene. The authors advocate the use of LDH after surgery for pilonidal sinus as it decreases the chance of recurrence. According to the authors, larger studies with long-term follow-up are still needed to approve this conclusion.

Sixty patients who underwent surgical treatment of pilonidal sinus disease and were treated with a 755-nm alexandrite laser after surgery were examined retrospectively. The charts were reviewed, and the patients were interviewed via phone about their post-laser period and recurrence. The overall recurrence rate was 13.3%, after a mean follow-up period of 4.8 years. The mean number of laser treatments was 2.7. Seventy-five percent of the recurrences were detected after a follow-up period of 5 to 9 years. Fifty percent of the recurrent cases had drainage and healing by secondary intention before LHD. The investigators concluded that LHR after surgical interventions in pilonidal sinus disease decreases the risk of recurrence over the long term. This study had no control group which limits the validity of the study's conclusion (Oram et al., 2010).

Badawy and Kanawati (2009) evaluated the effectiveness of LHR in the natal cleft area on the recurrence rate of pilonidal sinus disease as an adjuvant therapy after surgical treatment. The study included 25 patients. Fifteen patients underwent LHR treatment using Nd:YAG laser after surgical treatment (patients group) while ten subjects had surgery alone and did not undergo LHR control group. The patients received 3 to 8 sessions of LHR. The follow up period lasted between 12 to 23 months. None of the patients who underwent LHR required further surgical treatment. Seven patients out of ten in the control group developed recurrent disease. The investigators concluded that LHR should be advised as an essential adjuvant treatment after surgical treatment of pilonidal sinus disease. This study is limited by a small sample size and lack of randomization.

## Professional Societies

### American Society of Colon and Rectal Surgeons (ASCRS)

The ASCRS guidelines for managing pilonidal disease state that elimination of hair from the gluteal cleft and surrounding skin, by shaving or laser epilation, may be used for both acute and chronic pilonidal disease in the absence of abscess as a primary or adjunct treatment measure. Weak recommendation based on low-quality evidence (Johnson et al., 2019).

## U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

### Phototherapy

A number of different phototherapy devices have been approved by the FDA. These include devices that deliver blue, green, and yellow light phototherapy; photothermolysis devices, intense pulsed dye lasers, and near-infrared lasers. See the following website for more information (use product codes FTC or GEX):

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. (Accessed October 5, 2020)

### Photodynamic Therapy

A number of different photodynamic therapy devices have been approved by the FDA. See the following website for more information (use product code MVF): <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>.

(Accessed October 5, 2020)

### Pulsed Dye Laser (PDL)

PDLs are classified as Class II devices. In 1986, the Candela Corporation manufactured the first PDL approved by the FDA for the treatment of cutaneous vascular lesions. Since then, various models have been developed and deemed substantially equivalent by the FDA. See the following website for more information (use product code GEX):

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. (Accessed October 5, 2020)

### Laser Therapy

Several flashlamp-pumped pulsed dye lasers (FLDPLs), Xenon-chloride (XeCl) excimer lasers, and erbium:yttrium-aluminum-garnet (Er:YAG) lasers have received FDA approval. See the following website for more information (use product code GEX):

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. (Accessed October 5, 2020)

### Additional Products

PDLs include but are not limited to the following: C-beam Pulse Dye Laser System (Candela Corp.); PhotoGenica V Star and PhotoGenica V lasers (Cynosure, Inc.).

The complete list of commercially available devices for light therapy and laser therapy for rosacea is extensive. Some examples are the PhotoGenica V (Cynosure Inc.); Photoderm® VL/PL; and VascuLight™ Elite, HR, SR, and VS (Lumenis Inc.); 532-nm KTP laser (Gemini, Laserscope); 585-nm flashlamp pulsed dye laser 595-nm flashlamp pumped long-pulsed PDL (V-beam, Candela); GentleLASE (Candela Laser Corp., Candela Corp.); LightSheer EP (Lumenis Inc./Yokneam); Coolglide Vantage (Altus/Cutera Inc.); Apogee 5500, Apogee 6200 (Cynosure Inc.); Vasculite Plus Intense Pulsed Light laser (Lumenis Inc.).

PDT products include but are not limited to the following: BLU-U(TM) (DUSA Pharmaceuticals Inc, Wilmington, MA), Levulan® Kerastick® (DUSA Pharmaceuticals Inc, Wilmington, MA), Metvix® or Metvixia® (PhotoCure ASA, Oslo, Norway).

The following phototherapy devices are available for treatment of AV:

- *Blue Light:* ClearLight Acne Photoclearing System (Lumenis, Santa Clara, CA), BLU-U 4170 (DUSA Pharmaceuticals, Wilmington, MA), OmniLux Blue (Phototherapeutics, Manchester, UK)
- *Green Light:* 532 nm Aura Laser and 532/1064 nm Gemini laser (Laserscope, San Jose, CA)
- *IPL Sources:* ClearTouch (Radiancey Inc., Orangeburg, NY), Ellipse (DDD, Horsholm, Denmark), Estelux™ System (ICN Photonics Ltd., Llanelli, UK)

- *Near-infrared Lasers*: Smoothbeam (Candela, Wayland, MA), CoolTouch CT3 (CoolTouch Inc., Roseville, CA), Aramis (Quantel, Clermont-Ferrand, France)

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## Policy History/Revision Information

Date	Summary of Changes
04/01/2021	<p><b>Template Update</b></p> <ul style="list-style-type: none"> <li>Removed <i>Related Policies</i> and <i>CMS</i> sections</li> <li>Updated <i>Instructions for Use</i>; replaced reference to “MCG™ Care Guidelines” with “InterQual® criteria”</li> </ul>
11/01/2020	<p><b>Template Update</b></p> <ul style="list-style-type: none"> <li>Reformatted policy; transferred content to new template</li> </ul> <p><b>Title Change</b></p> <ul style="list-style-type: none"> <li>Previously titled <i>Light and Laser Therapy for Cutaneous Lesions and Pilonidal Disease (for Louisiana Only)</i></li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Updated <i>Clinical Evidence</i>, <i>FDA</i>, <i>CMS</i>, and <i>References</i> sections to reflect the most current information</li> <li>Archived previous policy version CS069LA.K</li> </ul>

## Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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